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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,843	05/18/2006	Lorenza Gonzalez-Mariscal	UHT1.001APC	2198

20995 7590 04/28/2011  
KNOBBE MARTENS OLSON & BEAR LLP  
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IRVINE, CA 92614

EXAMINER
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BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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04/28/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/540,843	<b>Applicant(s)</b> GONZALEZ-MARISCAL ET AL.	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/14/2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-16,22,23,31,43,45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9,16,22,23,31 and 43 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/27/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/2011 has been entered.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Election/Restrictions**

This application contains claims 10-15 are drawn to species nonelected without traverse in the reply filed on 10/7/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 8, 9, 16, 22, 23, 31, 43, 45 and 46 are examined on the merits. Claim 46 is new and claim 8 has been amended to include new limitations.

### **Response to Arguments**

Applicant's arguments with respect to claims 8, 9, 16, 22, 23 and 43 have been considered but are moot in view of the new ground(s) of rejection.

**Claim Rejections - 35 USC § 102**

**(New Rejection Necessitated by Amendments)** Claims 8, 9, 16 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al. (Molecules and Cells, 1999).

The claimed invention is drawn to a pharmaceutical composition for the delivery of a therapeutic agent, which comprises the agent and an effective amount of a VP8 rotavirus protein or a derived peptide thereof or mixtures thereof. The therapeutic agent can be a peptide with biological activity and the composition is formulated for oral administration and contains a pharmaceutically acceptable vehicle. The VP8 protein or derivative thereof induces the opening of tight junctions between epithelial or endothelial cells, thereby enhancing passage of said therapeutic agent through epithelia or endothelia.

Kang et al. teach generation of recombinant, full-length rotavirus VP8 protein and its use eliciting antibodies in the intestine. In order to achieve this, Kang et al. teach administration of the VP8 protein orally to mice in PBS (a pharmaceutical vehicle). Kang et al. also teach that by adding the biologically active peptide of Cholera Toxin (CT), which functions as an adjuvant, IgA response/titer was increased. See page 615. In addition, Kang et al. teach the encapsulation of the recombinant VP8 in order to improve the delivery of the antigen to the intestinal region of the host, thereby improves the localize antibody responses against the antigen. While Kang et al. does not discuss the use of VP8 to open the tight junctions of between epithelial or endothelial cells which permits passage of the therapeutic agent through these cellular layers, they do teach the structural requirements of the claimed invention of a VP8 rotavirus combined with a biologically active peptide (Cholera Toxin). As a result, their teachings generate a composition

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capable of altering the cellular organization according to the claimed invention. Therefore, Kang et al. anticipate the claimed invention. See pages 613-614.

### **Claim Rejections - 35 USC § 103**

**(New Rejection Necessitated by Amendments)** Claims 22, 23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. as applied to claims 8, 9, 16 and 43 above, and further in view of Langer and Chen (US Pat. 6,004,534).

In addition, the claimed invention requires that the biologically active peptide can be a hormone, such as insulin.

Langer and Chen teach the use of encapsulated insulin in liposomes for delivery to a host via the oral route. They also teach that the liposomes can be modified with viral or bacterial proteins that possess an affinity for cell surface proteins on the intestine. However, Langer and Chen do not teach the use of rotavirus VP8. See columns 7 and 8.

The teachings of Kang et al. are discussed above, however, they do not teach the combination of insulin or another hormone with the encapsulated rotavirus VP8 protein.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Langer and Chen in order to encapsulate insulin with the VP8 protein of the rotavirus. One would have been motivated to do so, given the suggestion by Langer and Chen that in addition to encapsulating insulin for oral administration, viral antigens with an affinity towards cellular receptors/surface molecules can also be added to the encapsulated substance in order to target it to the virus specific cell. There would have been a reasonable expectation of success, given the knowledge that the rotavirus VP8, which is involved with virus-cell interactions, can

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be encapsulated for oral administration and induction of IgA antibodies in the intestine of the host, as taught by Kang et al. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### **Claim Objections**

Claims 45 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusion**

No claims are allowed. SEQ ID NO:s 2, 3 and 7 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/  
Examiner  
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